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UNITED STATES ARMY MEDICAL MATERIEL DEVELOPMENT ACTIVITY

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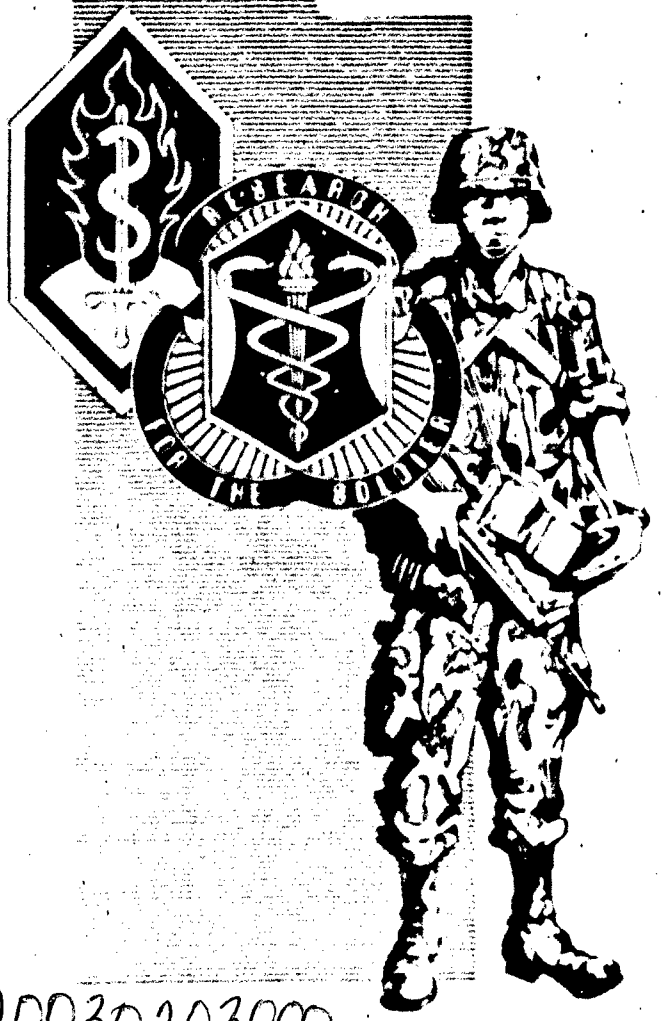
1988 ANNUAL REPORT



FORT DETRICK, FREDERICK, MD 21701-5001

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10 MARCH 1989

ANNUAL REPORT FOR PERIOD 1 JANUARY 1988 - 31 DECEMBER 1988

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U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
FORT DETRICK
FREDERICK, MARYLAND 21701-5012

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The Annual Report, Calendar Year 1988, summarizes development projects monitored by the U.S. Army Medical Materiel Development Activity in projects authorized by the Surgeon General, the Army, and the Commander, U.S. Army Medical Research and Development Command, and supported by RDTE funds from the U.S. Army Medical Research and Development Command.

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U.S. ARMY
MEDICAL MATERIEL DEVELOPMENT ACTIVITY

1988 ANNUAL REPORT

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INTRODUCTION

This report is a synthesis of the accomplishments of the U.S. Army Medical Materiel Development Activity (USAMMDA) during calendar year 1988. As both USAMMDA and the Medical Materiel Acquisition Management (MEDMAM) process have continued to mature and be refined, the emphasis within the organization has been placed on improving accountability, and ensuring that the Medical Materiel Development Program is aligned with the requirements of the Army Medical Department (AMEDD) in consonance with the needs of the Army.

While the mission of the materiel developer is well defined in pertinent regulations, some conflict still remains within the medical community at both Department of the Army and Department of Defense (DOD) levels as several activities and agencies continue to fulfill that mission without clearly defined responsibilities. USAMMDA's management initiatives during the past year have been focused on improving the efficiency of the MEDMAM process.

To this end, USAMMDA is sponsoring a comprehensive study by the Logistics Management Institute (LMI) to review the entire spectrum of medical materiel acquisition within the Army, and to make recommendations to improve the efficiency of that process. The study involves all the primary participants within the AMEDD to include the materiel developer, combat developer, logistician, trainer, and tester, as well as participants at the Defense Personnel Support Center (DPSC) and Defense Medical Standardization Board (DMSB).

The staff has established a Quality Assurance (QA) program paralleling the program established by HQ, U.S. Army Medical Research and Development Command (USARMDC). As USAMMDA is not directly involved in patient care, our QA program is focused on ensuring the quality of the medical materiel development program in meeting the Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) requirements of the Code of Federal Regulations.

We initiated a formal Review and An (R&A) Program in 1988. This is a semiannual overview of the status of all development activities conducted by the USAMMDA and is focused on schedule, cost, performance, and major project support functions in support of our QA initiatives.

The 1988 U.S. Army Medical Research, Development, and Acquisition Mission Area Materiel Plan (MAMP) was completed based upon a joint conference during which nearly 100 of our development products were assessed. This effort satisfied the HQDA requirement for providing a legitimate basis for the prioritization of the Medical RDA program. Conference participants have become acutely aware of the value of the process, as well as the need to broaden the scope of our assessments. The next MAMP has been scheduled for March 1989 and will review 100% of USAMRDC development products as well as selected predevelopment and nondevelopmental items of AMEDD interest.

The Program Executive Office (PEO) for Health Care Systems was disestablished by a decision memorandum dated 21 June 1988 from the Office of the Under Secretary of the Army (Army Acquisition Executive). While the medical PEO office was eliminated, USAMMDA still continues to fulfill selected PEO functions within extant manpower ceilings.

In summary, this has been an exceptionally busy and productive year. Our work goes on at a relatively hectic pace with proactive management being challenged by intermittent crises. Our involvement in programs of highest Army and AMEDD interest keeps us all intellectually stimulated in our efforts to provide only the highest quality products for our soldiers in the field.

CARL E. PEDERSEN, JR.
Colonel, MS
Commanding

PROGRAM MANAGEMENT

INTRODUCTION

Program wide management support is the primary function of the Project Management Support Division (PMSD), providing centralized administrative, financial management, contracting, and logistical support. Its mission, goals, and military relevance coincide with those of the Project Management Divisions collectively. Throughout 1988, the emphasis within PMSD has been on enhancing the support provided to the Project Management Divisions, and improving the accountability for resources throughout the AMEDD materiel development arena.

MAJOR ACCOMPLISHMENTS

- 1988 Medical RDA MAMP: The FY88 Medical RDA Mission Area Materiel Plan (MAMP) Conference was convened 29-30 June 1988 to conduct product assessments for evaluating the USAMRDC Research, Development, and Acquisition (RDA) Program with respect to medical-related combat requirements. Representatives from USAMRDC, USAMMDA, USAMMA, Office of The Surgeon General (OTSG), Academy of Health Sciences (AHS), and other Training and Doctrine Command (TRADOC) schools considered 96 products against 12 Medical Mission Area Development Plan (MADP) capability issues, and seven medical-related Battlefield Development Plan (BDP) capability issues. AMEDD prioritization was developed and was approved by the Commanding General, USAMRDC and the Commandant, AHS. The increased participation by other AMEDD organizations, non-AMEDD organizations, and other Services greatly enhanced conference effectiveness. In addition, overnight turnaround on the team scoring resulted in very enlightening discussions in the final general session.

- Project Management Control System (PMCS): Contractor development of the Project Management Control System (PMCS) was extended to March 1989 to complete the revision of the Schedule Module. The revision will result in the following enhancements: streamlined user interface, unified Oracle data management design, and capability to perform across-schedule queries. Complete documentation will be provided. The Work Breakdown Structure (WBS) code in the Schedule Module was standardized and mandatory commander level tasks to be included in R&A briefings were identified. Training on the Schedule Module and BPL were provided by the contractor to USAMMDA personnel as required.

• Automatic Data Processing Support: During 1988, USAMMDA procured additional Zenith computers to allow more users the capability to access commercial software packages. To promote greater compatibility between USAMMDA, USAMRDC, and other activities, each computer was equipped with standard software packages: a terminal emulation package (ST240), a spreadsheet package (Lotus 1-2-3), a word processor (Word Perfect), and a data base manager system (dBase III). Additional software packages (such as BMDP Statistical Software and Master Graphics Series) were purchased to increase specific user productivity. Macintosh SE's were introduced to improve the quality of presentation graphics and provide a totally supportive environment for all users. With the conversion to Macintosh for graphics, USAMMDA is able to produce high-quality graphics output in-house; thereby eliminating the need to contract for such services. Word Perfect 4.2 in a PC environment became the standard word processing package for all users.

• Configuration Management Support: A project was initiated to study the problem of configuration management (CM) for the technical data generated in the development of products by USAMMDA. Three alternatives were investigated; in-house CM, contract CM, other government agency support for CM. The most promising solution to the problem is using another government agency to provide this support. The CM office at Belvoir Research, Development and Engineering Center has indicated a strong interest in providing this support for USAMMDA. Communication and coordination is being set up to work out the details of how to get the program setup and underway.

• Testing: Logistics Management Branch has become the focal point for coordination of medical materiel testing requirements within USAMMDA. All user test requirements are forwarded to the AMEDD Board at the Academy of Health Sciences. During 1988, one user test was conducted by the Board. Fifteen additional user tests are currently scheduled through FY91.

Clinical trials for USAMMA developed vaccines are considered technical tests. When USAMMDA wants to target a military population, i.e., a FORSCOM Unit, for these clinical trials, the requirement must be coordinated through the DA, Test Schedule and Review Committee (TSARC) process. This process has been successful. Tests of two vaccines were completed in 1988 where volunteers were solicited from designated FORSCOM Units. Five additional such tests are currently scheduled through FY91.

• MANPRINT Focus: The Logistics Management Branch is the responsible organizational element for managing the Army Manpower and Personnel Integration (MANPRINT) program within USAMMDA. This includes the incorporation of MANPRINT requirements into all developmental products as well as performing the necessary coordination with other interested MANPRINT participants and following up to ensure that the MANPRINT requirements are satisfied. All USAMMDA logistics management personnel have received formal training in MANPRINT.

• INTEGRATED LOGISTICS SUPPORT: All Integrated Logistics Support (ILS) documentation necessary for the development of USAMMDA products has been completed within established product milestone guidelines. These documents include; ILS Plans, Configuration Management Plans, Transition Plans, System Support Packages, Basis of Issue Plan Feeder Data Sheets and Qualitative and Quantitative Personnel Requirements Information Sheets. Additionally, Logistics Management Branch has maintained close coordination with other Government agencies interested in the fielding of USAMMDA products.

HUMAN RESOURCES

• USAMMDA Key Personnel:

Position	Name	Date
Commander	COL C.E. Pedersen, Jr.	1 Jan 88 to 31 Dec 88
PM/AMSPMD	COL B.A. Schiefer	1 Jan 88 to 31 Dec 88
PM/BSPMD	Dr. W.E. Brandt	1 Jan 88 to 31 Dec 88
PM/PSPMD	COL R.O. Pick	1 Jan 88 to 31 Dec 88
Dir/PMSD	MAJ J.L. Chaffee	1 Aug 88 to 31 Dec 88
	LTC R.H. Perry (Acting)	1 Jan 88 to 31 Jul 88

• USAMMDA Strength: As of 31 December 1988:

	Military	Civilian	Total
Required	25	51	76
Authorized	21	36	57
Actual	16	30	46

FISCAL PERFORMANCE

• In-House: USAMMDA in-house fiscal execution exceeded DA established targets for fiscal year 88, and exceeded FY87 performance by 5%.

	Allotment	Obligations	Disbursements
FY88 Dollars ($000)	4,156	4,066	2,457
Target (%)		95	49
Actual (%)		98	59

• Program Wide: Performance in the command-wide development program was not as successful. Both laboratory and extramural program performance was below target in terms of obligations. Critical disbursement targets were met in-house but not in the contract program. Significant delays were encountered in applying contract modifications.

		PERCENT					
	Allotment	In-House		Extramural		Total	
Project	($000)	OBL	DISB	OBL	DISB	OBL	DISB
836	11,362	77	49	88	11	86	18
808	4,689	86	71	97	23	94	37
809	7,555	71	42	88	22	83	28
993	22,191	93	66	93	14	93	19
Total 6.3B	45,797	81	55	92	15	90	22
832	2,709	98	59	92	75	95	68
847	6,659	74	54	97	66	92	63
848	3,894	100	61	70	28	73	30
849	1,868	75	58	94	42	88	46
Total 6.4	15,130	85	57	88	53	87	54
Total Program	60,927	82	56	91	24	89	30

APPLIED MEDICAL SYSTEMS
PROJECT MANAGEMENT DIVISION

THE PROGRAM

INTRODUCTION

The Applied Medical Systems Project Management Division is a multidisciplinary team with broad mission responsibilities to centrally manage the development and initial production of applied medical products, related diagnostic equipment, visual corrective devices for protective masks, and pesticide delivery systems.

MILITARY RELEVANCE

Applied Medical Systems is committed to developing compact, lightweight, durable medical equipment to achieve both the Army's demanding Service-unique and multi-Service mission requirements. Diverse, multi-discipline technologies are integrated to create a wide range of state-of-the-art systems. Equipment initiatives are directed toward addressing medical defense against chemical warfare agents, medical protection against military hazards, and the ability to provide care to the combat casualty.

OBJECTIVES

Army readiness is predicated upon the timely and successful execution of programs by the Materiel Developer. To achieve this, Applied Medical Systems capitalizes on emerging Tech Base efforts and aggressively manages the development component of the AMEDD Research, Development and Acquisition process to meet DA and Joint Services performance and supportability requirements for field-survivable medical equipment.

PRODUCT DESCRIPTIONS

- The High Capacity X-ray System is a radiographic and fluoroscopic unit incorporating state-of-the-art solid state electronics, composite materials for lightweight construction, and mil-spec components for system reliability that complies with all radiation health and safety standards and meets the requirements for military operation.

- The Field Medical Oxygen Generation and Distribution System (FMOGDS) will provide both bedside and cylinder-refill oxygen capabilities within TOE hospitals and medical logistics organizations. The system is designed to reduce the logistics burden of acquiring medical grade oxygen.

- The Resuscitative Fluids Production and Reconstitution System (REFLUPS) produces sterile Water for Injection from a potable water source, combines that water with concentrated electrolytes to formulate parenteral solutions, and packages the solutions in sterile IV bags.

- Laser Eye Protection consists of prescription eyewear which affords laser protection against low energy (1 joule) lasers. The eyewear is designed to attenuate laser beams emitted from target designators, range finders, and low energy laser weapons. Development of this eyewear entails fabricating polycarbonate substrate and applying absorptive dyes, reflective holograms, and dye-hologram hybrid technologies.

- Ballistic Eye Protection consists of prescription eyewear which affords ballistic protection against small mass (5.8 grain) and low velocity (640-660 feet per second) fragments. The eyewear is fabricated from polycarbonate and designed in two versions, clear and tinted.

- The Steam Vacuum Pulse Sterilizer System (SVPSS) is a microcomputer-controlled automatic steam sterilizer which employs a pressure/vacuum pulsing-conditioning principle for air removal and is designed to sterilize instruments, linens, and solutions for a field hospital.

- The Ethylene Oxide Sterilizer (EOS) is being designed as a stand alone device for sterilizing non-heat sensitive devices as well as those sensitive to moisture or heat or those damaged by steam or liquid chemical sterilization. Products that fall into the latter categories include any plastic or rubber products such as catheters, resuscitation bags, anesthesia masks, surgical gloves, and most fiber optic instruments.

- The Special Operations Forces Sterilizer is a rugged, compact, lightweight, easy-to-use steam sterilizer for the Special Operations Forces medical personnel operating in mobile or unconventional warfare modes. This sterilizer can use electricity, wood fires, or gasoline/kerosene stoves as a heat source.

- The Field Computed Tomography Scanner weighs about 1,600 pounds, requires less than ten kilowatts of power, can be deployed in a 1:1 ISO Shelter, produces diagnostic quality CT information, and because of the thermal management design, can be operated continuously.

- The Digital Imaging Network System will provide an integrated filmless imaging acquisition, display, network, and archiving capability for field use.

- The X-Ray System, Dental, Miniature (XRSDM) is a small, lightweight, hand-held dental x-ray system for field use. The system consists of a hand-held x-ray generator subsystem (suitable for use with self-developing film or digital imager) and a digital imaging and storage subsystem for displaying images without the use of film.

- The Powered Ventilator is a lightweight portable device which uses an oxygen source or filtered ambient air to resuscitate and ventilate apneic casualties that are being medically evacuated. The ventilation can be administered through either an oropharyngeal mask or a cricothyroid cannula.

- The NBC Casualty Vital Signs Monitor will noninvasively determine the heart rate and blood pressure of a casualty in chemical protective clothing while in a battlefield environment.

- The Life Detector is a hand-held device which provides a noninvasive method for detecting heart beat, respiration, or some other indicator of the presence of life, through chemical protective clothing without compromise to the protective ensemble or individual, and determining the adequacy of prior antidotal treatment.

- M-40 CB Protective Mask Vision Correction, Mainstream is a vision correction device which uses the M-17 wire optical insert with modified supporting hoops and is internally mounted in the M-40 CB protective mask.

- M-40 CB Protective Mask Vision Correction, Pre-Planned Product Improvement is a vision correction device which uses the B-LPS prescription lens carrier and is internally mounted in the M-40 CB protective mask.

- The Electronic Wet Bulb Globe Temperature Monitor (WBGT) will be available for use in field units to measure Dry Bulb Temperature (DBT), Wet Bulb Temperature (WBT), and Globe Temperature.

- The Hand-held, Heat-stress Calculator contains a prediction algorithm capable of computing work/rest cycles and associated water requirements for the individual soldier under a variety of environmental conditions.

- The Computer Assisted Post-Mortem Identification System consists of computer hardware and a software routine that compares antemortem and postmortem dental records to yield a list of most probable matches for facilitating the process of identifying human remains.

- The UH-60 External Rescue Hoist (EMRH) will be mounted on UH-60A (Black Hawk) Medical Evacuation (MEDEVAC) helicopters. It will provide 25 to 33 percent more space inside the aircraft compared to the current internally mounted rescue hoist. The additional cabin space can be used for patient care, medical equipment, and the MEDEVAC litter kit. Use of the EMRH will decrease mission time required for extraction of casualties or personnel and decrease aircraft weight.

- The Operating and Treatment Unit, Dental, Field (OTUDF) is a small, lightweight, mobile dental unit which will be used to provide emergency, limited preventive, and sustaining dental care in the field. It consists of a light source, suction apparatus, water reservoir, and high and low speed drills.

- The Decontaminable Folding Litter is capable of being decontaminated and providing a surface on which patients can be CWA decontaminated. It consists of aluminum poles and spreader bars, polypropylene mesh, retractable nylon handles, and ethylene-propylene-diene-monomer (EPDM) securing straps.

- The CW Resistant Field Dressing Cover consists of a strip of cotton gauze sandwiched between two laminates of polyethylene/nylon/polyethylene (PNP). The cover is used over the field battle dressing to protect open wounds and prevent penetration by chemical warfare agents.

- The CWA Protective Patient Wrap is a disposable fabric container to protect decontaminated or uncontaminated patients from chemical agents during evacuation in a field environment.

- The new Field Medical Refrigerator will replace the current refrigerator used to contain blood and biologics which has become logistically unsupportable.

- The Optometry Field Set contains field operational optometric equipment which is composed of an examinee chair, instrument pole, examiner-examinee stools, supporting accessories, commercially available optometric instrumentation-equipment, and field chests. Acquisition requirements call for the production of 343 Optometry Field Sets, 173 in one chair/two stool configuration for optometrists and 170 in one chair/one stool configuration for flight surgeons.

• The lightweight, mobile Ultrasonic Imaging System is being developed by the Navy for field and shipboard use. The Navy's contractor promises to produce images superior to any commercial device currently available.

• The Individual Chemical Resuscitation Device (RDIC) provides manually operated positive pressure respiratory resuscitation to assist in the restoration of normal breathing of a battlefield casualty. The RDIC filters chemical warfare agents from ambient air and is usable with an oropharyngeal mask or cricothyroid cannula.

• The Molecular Sieve Oxygen Generating System (MSOGS) will be used for trauma and chemical agent patient resuscitation on Medical Evacuation (MEDEVAC) aircraft.

MAJOR ACCOMPLISHMENTS

• Two test prototypes of the High Capacity X-Ray System which have been in use in the field for over one year have accumulated a total of over 50,000 exposures each with no major flaws. The TDP is over 90 percent complete and will be available for competitive bids by the end of February 1989. Three low rate initial production units were delivered this year.

• After the first Milestone II In-Process Review (IPR), the Field Medical Oxygen Generation and Distribution System developmental contract was placed into a reduced level of effort while acquisition and testing of an NDI was accomplished. A MEPECC model M1-B was acquired and user and technical testing were conducted during the 3Q88 and 4Q89. Technical testing, along with a hazard analysis, was performed by Dayton T. Brown and VSE Corporation, respectively. A Milestone IIa IPR was conducted in late November 1988 which provided a dual track strategy. The dual strategy consists of pursuing an NDI acquisition while continuing a developmental effort. If an NDI proves acceptable, then that system will be type classified for fulfilling Army medical needs. A TWG was convened on 15 December 1988 to discuss testing issues and update the TEMP for the FMOGDS project while NDI acquisition and developmental contract initiation was ongoing.

- The delivery of the Resuscitative Fluids Production and Reconstitution System (REFLUPS) Advanced Development Models was completed in March 1988. Systems were delivered to the U.S. Army Medical Department Board, the Naval Ocean Systems Center, and the Naval Blood Research Laboratory for extensive technical and user tests. The Concept Evaluation Program (CEP) testing was also completed in March. A Special Tri-Service General Officer Review was held in May to discuss the project's progress and issues. The major technical issue, regarding FDA approval, was resolved in a meeting held in July when the REFLUPS reverse osmosis filtration technology was stated to be approvable. Monthly Technical Interchange Meetings, Joint Working Group Meetings, and Integrated Logistics Support Meetings were held throughout the year to ensure progress correcting deficiencies found during the technical and user tests and to update the Program Management Documentation. The Critical Design Review was conducted in December.

- Initial fielding of Ballistic-Laser Protective Spectacles commenced on 16 May 1988 at Camp Pendleton, CA. Mainstream effort has successfully developed and acquired protection against two wavelength laser threats to meet immediate needs of high priority contingency forces. Product improvement efforts will be directed towards developing protection against three and more wavelength laser threats. Of the 100,000 Ballistic-Laser Protective Spectacles kits contracted on 3 September 1987 for low-rate initial production, 10,140 were delivered to high priority contingency forces this year. Follow-on Concept Evaluation Program testing was initiated in December 1988 to revalidate user operational performance and acceptance.

- The Steam Vacuum Pulse Sterilizer System (SVPSS) Logistics Demonstration was conducted in mid-July 1988. An Initial Operational Test and Evaluation (IOTE), two Scoring Conferences, and Environmental Testing were completed in November. The contract is in its final year with delivery of the SVP units expected 4Q89.

- A contract modification for the Ethylene Oxide Sterilizer (EOS) was awarded this year to provide the funding for contract completion.

- The USABRDL-designed Special Operations Forces Sterilizer was transitioned to USAMMDA in February 1988. In April 1988, a JWG concurred that revision to the TDP was the major requirement at hand. This was accomplished, and a correspondence Milestone I/III IPR transitioned the device to USAMMA in 4Q88.

- The development of a compact, lightweight, energy efficient Field Computed Tomography Scanner demonstration prototype was completed ahead of schedule this year. The scanner was displayed at the Radiological Society of North America (RSNA) meeting in November.

- An overall project study plan for the Digital Imaging Network System was published and Joint Services Operational Requirement was drafted in September 1988. Clinical evaluation of a latent phosphor plate imager was begun at three selected military sites. A network evaluation of a DEPMEDS hospital using ruggedized imaging work stations was also initiated.

- The Miniature Dental X-Ray progressed smoothly with delivery of the first engineered prototype in 4Q88 and an expected delivery of four units per month thereafter. The Imager Subsystem provided many challenges as technological difficulties caused costs to climb. A stop work order was issued in 4Q88. After several months of negotiations between the National Bureau of Standards, the prime contractor, and EO Engineering Products, Inc., the subcontractor working on the imager, initiated a proposal acceptable to all parties which will provide USAMRDC a testable prototype within the scope of work and within the total allocated budget. A Joint Working Group (JWG) was convened 1 November 1988 to address testing issues and to finalize the JSOR. In November, the Vice Chief of Staff of the Army, General Brown, was briefed on the XRSDM progress during the Logistic Center's Materiel IPR. A special JWG was convened to update management on the direction and potential acquisition strategies available for this system.

- Technical Testing (TT) and ranking according to overall performance of various commercial Powered Ventilators were completed. An expert panel met in 1Q89 to determine Tri-Service resuscitation requirements for Echelons II, III, and IV medical care. The revised JSOR was completed to reflect the panel's conclusions.

- A Milestone 0/I IPR transitioned the Vital Signs Monitor into Demonstration/Validation in November 1988.

- The Life Detector Personal Monitor and Communicator (PMC) contract with Purdue University demonstrated the first deliverable with success. A contractual effort, using microwave technology, managed by U.S. Army Belvoir Research Development and Engineering Center (USABRDEC) and involving Georgia Tech Research Institute (GTRI) and Michigan State University (MSU) was initiated that entails using the two universities' expertise in various aspects of microwave technology to develop a microwave reflectance device which will obtain heart rate from a distance. An IPR was held in 1Q89 to resolve the major issue affiliated with this program.

- Initial fielding of M-40 wire inserts commenced on 8 September 1988 at U.S. Army Chemical School, AL.

- In December, USACRDEC and USAMRDC representatives at a Preliminary Design Review selected two different mounting system concepts for prototype fabrication of the M-40 CB Protective Mask Vision Correction, Pre-Planned Product Improvement.

- Currently, the U.S. Army Research Institute of Environmental Medicine (USARIEM) is constructing a Military Specification for Electronic Wet Bulb Globe Temperature Monitor (WBGT).

- A Tri-Service meeting was held 4Q88 to discuss the program and to determine other service interest and requirements for the Hand-held, Heat-stress Calculator. In 1Q89, the AHS deleted the requirement for this project from the Capstone O&O Plan for Environmental Health Monitoring Equipment.

- The Quartermaster School was identified as the Combat Developer, and the Logistics Center was identified as the Logistician for the Computer Assisted Post-Mortem Identification System in 3Q88. The Quartermaster School has prepared and staffed the initial requirements document, a Mission Element Needs Statement (MENS). Preparations were made for a Milestone O/I IPR.

- A UH-60 External Rescue Hoist (EMRH) was installed on USAARL's UH-60 for Technical Testing. A Statement of Work is in the final phases of being staffed and will be incorporated into a Request For Proposal which will support the development of a wireless remote control communication pendant for the hoist.

- A TIWG for the Operating and Treatment Unit, Dental, Field (OTUDF) was convened in April 1988 after the Market Investigation was completed which defined the essential characters, and recommended conducting a Correspondence IPR and transitioning to USAMMA for a Basic NDI acquisition. After full staffing through DA, the system was further refined. Consequently, the Correspondence IPR process was initiated in August and completed during 1Q89.

- A Special IPR for the Decontaminable Folding Litter was held on 27 June 1988 which transitioned the Litter into the Production and Deployment phase of development. Request for Standardization was submitted to Defense Medical Standardization Board (DMSB) on 1 August 1988.

- A Milestone III IPR was held on 20 January 1988 which transitioned the CW Resistant Field Dressing Cover into the Production and Deployment phase of development. A request for standardization was submitted to the DMSB and the TDP was sent to the Defense Personnel Support Center to initiate production.

- A Milestone III IPR was held 22 October 1987 for the CWA Protective Patient Wrap. A Milestone III IPR was held 22 October 1987. FY88 events have centered around resolving several doctrinal issues before formal transition to USAMMA can be accomplished.

- A JWG held 12 January 1988 to determine the essential characteristics for the Field Medical Refrigerator, and a Correspondence Milestone II IPR on 25 May 1988 approved moving it into the Production and Deployment phase. Formal transitioning to USAMMA occurred on 2 June 1988.

- A production contract for the Optometry Field Set was awarded on 20 September 1988 to Atlantic Industries, Inc. The work effort this year consisted of monitoring non-standard item production and standard item integration for fielding.

- The Army monitored the Navy's development effort of the Ultrasonic Imaging System this year. The Army has expressed no further interest in this development and has decided to terminate all future efforts on this product until the Combat Developer has a recognized requirement.

- A Joint Services meeting was held in 1Q89 to discuss far forward resuscitation and the need for the Individual Chemical Resuscitation Device (RDIC), considering the subsequent fielding of pyridostigmine. A final decision regarding the need for the RDIC has not been made. The Required Operational Capability (ROC) for the RDIC was revised this year.

- A draft O&O Plan for the Molecular Sieve Oxygen Generating System (MSOGS) was written on 30 August 1988. A JWG to finalize the System MANPRINT Management Plan was held on 15 November 1988. Once the requirement for the MSOGS is approved, it will be incorporated into AVSCOM's ROC for On Board Oxygen Generating System (OBOGS).

- The Patient Holding and Evacuation Heater Units were issued to the 6th MED BN (Alaska) in February 1988.

- Fielding of the Wheeled Litter Carrier began in July 1988.

PROJECTIONS

- Procurement of the High Capacity X-Ray System could start as early as 1989.

- Phase II of the Field Medical Oxygen Generation and Distribution System (FMOGDS) development contract with Guild Associates, Inc. will begin early in the 3rd Quarter of FY89. Technical and user testing of NDI oxygen generators will be conducted by the U.S. Army Test and Evaluation Command and the Academy of Health Sciences, U.S. Army, respectively, starting in the 4th Quarter of FY89.

- The REFLUPS will move into the Full Scale Development Phase in August 1989. Life Cycle Cost estimates, determined from the Abbreviated Analysis to be driven by the process consumables, will be substantially reduced.

- Development of third wavelength Laser Protective Spectacles will be initiated in March 1989.

- The Steam Vacuum Pulse Sterilizer System contract is in its final year with delivery of the SVP units expected 4Q89. A Milestone IIIa IPR is scheduled in 1Q90.

- The Ethylene Oxide Sterilizer (EOS) first prototype unit is progressing toward initial technical testing. Prototypes and a complete TDP for this effort will be delivered in 1Q90.

- The Field Computed Tomography Scanner will undergo acceptance testing during the 2Q89. Computer and software will be upgraded to support a CEP test scheduled for the fall of 1989.

- A Milestone . IPR is anticipated for the Digital Imaging Network System in 4Q89.

- The Powered Ventilator will transition to Production and Deployment in July 1989.

- The Vital Signs Monitor will transition to Full Scale Development in November 1989.

- The Life Detector contracts' deliverables are expected in 3Q89 and Concept Exploration Program testing will be conducted in 1Q90 to test the three different developmental prototypes.

- The CAPMI will transition to Development Proveout in February 1989 and then transition to Production and Initial Deployment in September 1989.

- Technical testing of the UH-60 External Rescue Hoist (EMRH) is expected take place in 2Q89 to evaluate the concept.

- A correspondence IPR will transition the Field Dental Operating and Treatment Unit into Production and Deployment in January 1989.

- Low Rate Initial Production to validate the Technical Data Package of the Decontaminable Folding Litter will begin during 2Q89.

- The assignment of an NSN for the CW Resistant Field Dressing Cover is expected in 3Q89.

- Final transition of the TDP for the CWA Protective Patient Wrap to USAMMA is expected in 2Q89.

- Initial fielding of the Optometry Field Set is planned for September 1989.

- A prototype of the lightweight, mobile Ultrasonic Imaging System will be delivered to the Army during the second quarter of FY89.

- A Milestone II IPR for the RDIC will be held in March 1989 to either transition it into Full Scale Development or terminate the effort.

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BIOLOGICAL SYSTEMS
PROJECT MANAGEMENT DIVISION

THE PROGRAM

INTRODUCTION

The Biological Systems Project Management Division manages the development and acquisition of biological products to prevent casualties or loss of soldier effectiveness due to disease. These diseases may be naturally acquired (close contact, unsanitary conditions, contaminated environment, biting insects), or acquired by deliberate exposure to aerosols. Product Managers exploit domestic and foreign medical technology to remedy deficiencies identified by the Combat Developer and monitor research projects for their application to disease protective measures.

MILITARY RELEVANCE

Casualties from disease have been a major cause of hospital admissions and ineffectiveness on the battlefield. Figures for admission for soldiers during 1 year in Vietnam were as follows: disease - 70.6 percent; battle casualty - 15.6 percent; nonbattle injury - 13.8 percent. Efforts to reduce the impact of disease on operations will make a significant contribution to soldier effectiveness.

OBJECTIVES

This Division's directive is to develop effective preventive measures against diarrheal diseases; malaria; acute respiratory diseases; hepatitis; insect-transmitted diseases such as dengue and Japanese encephalitis; hemorrhagic fevers and other diseases spread by aerosol (and rapid methods to identify the cause of illness); schistosomiasis; meningococcal disease; and opportunistic wound infections. Methods to address these deficiencies (some of which include treatment) are vaccines, immune enhancers, adjuvants, immune globulins, antiviral drugs, insect repellents, and rapid identification kits for clinical specimens.

PRODUCT DESCRIPTIONS

- Insect/Arthropod Repellent Lotion is a long-lasting, user-acceptable, topically applied repellent to provide maximum protection for exposed skin from bites of insect/arthropod vectors of disease. This product recently completed the advanced development process, and the Defense General Supply Center is contracting for the first production run.

• Rift Valley Fever Vaccine was prepared by growing the virus in cultured monkey kidney cells at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) and the Salk Institute, inactivating the virus with formalin, and storing it as a lyophilized product. This investigational vaccine has been used in at-risk laboratory workers, United Nations peace-keeping forces, and State Department mission personnel. Licensure of the vaccine will be considered when new production runs are required to replace current stocks.

• J-5 Human Monoclonal Antibody is secreted by cultured hybridomas that were created by fusing myeloma cells with cells from the spleen of a person immunized with killed E. coli strain J-5. The collaborative effort between Walter Reed Army Institute of Research (WRAIR) and Centocor has shown that the monoclonal antibody, which reacts with the highly conserved lipid A region of the lipopolysaccharide, binds to a wide variety of endotoxins and to gram negative bacteria of many genera.

• Vaccinia Vectored Venezuelan Equine Encephalitis Vaccine (VEE) will be produced by inserting into a live vaccinia virus carrier the VEE genes that direct the production of immunizing VEE antigens. This vaccine should produce antibodies against both smallpox and VEE, and is being developed under contract by the Centers for Disease Control (CDC) to replace a live VEE vaccine that is reactogenic in 15 percent of recipients. It will be a contingency vaccine for biological warfare (BW) defense.

• Rapid Identification System for Biological Agents is a portable, rugged, easily operated system designed to identify biological agents in clinical materials. In the test, drops of serum from soldiers exhibiting symptoms of disease are placed on credit card sized blotters in plastic holders. After the reagents are added and absorbed, positive or negative results are visible to the unaided eye in less than 30 minutes.

• Argentine Hemorrhagic Fever Vaccine (AHF) is a live, attenuated vaccine for military personnel being deployed to endemic or potential BW threat areas with this agent. The vaccine was prepared by growing the virus in fetal rhesus monkey lung cells in a collaborative effort between USAMRIID and the Salk Institute. Following successful efficacy studies in Argentina, a license application will be prepared.

• N. meningitidis (Group B) Vaccine is a protein-based vaccine for use in conjunction with licensed polysaccharide vaccines to protect military personnel against epidemic cerebrospinal meningitis. The vaccine is a bacterial sub-capsular protein complexed to polysaccharide antigens. The product is a collaborative effort between WRAIR and Connaught Laboratories and is necessary to protect soldiers against a larger number of strains of this organism.

- Tularemia Vaccine is a live, attenuated vaccine for military personnel being deployed to an area where there is a potential threat use of Francisella tularensis as a BW agent. New lots of vaccine have been prepared at the Salk Institute under slightly modified production protocols, and are currently being tested for safety in volunteers at USAMRIID as well as being compared with older lots. There may be sufficient efficacy data for licensure.

- Ribavirin is an antiviral drug that has been shown to be effective against hemorrhagic and sandfly fevers. The Army is sponsoring a New Drug Application in order to have the product available for military physicians to treat diseases such ar Korean Hemorrhagic Fever and Lassa Fever.

- Shigella Vaccines are oral products containing live bacteria with specific antigens to protect against diarrheal diseases. These engineered vaccines are produced at WRAIR and tested at the University of Maryland Vaccine Testing Facility.

- Falciparum Malaria Sporozoite Vaccine is a product of recombinant DNA technology and consists of the circumsporozoite protein of Plasmodium falciparum. The vaccine is produced under a no-cost agreement with Smith, Kline and French. The vaccine is being tested in combination with different types of adjuvants in order to increase the antibody titers in volunteers.

- Vivax Malaria Sporozoite Vaccine is a product of recombinant DNA technology and consists of the circumsporozoite protein of Plasmodium vivax. The vaccine is following right behind the development of the falciparum malaria vaccine by collaboration between WRAIR and Smith, Kline and French; the most effective adjuvant for the falciparum vaccine will be given priority for the vivax vaccine.

- Hepatitis A Killed Vaccine was produced at WRAIR by growing the virus first in cultured monkey kidney cells and then in human lung cells until antigen concentrations reached a stationary level. The virus was inactivated with formalin, safety tested according to regulatory guidelines, and tested in volunteers. Several inactivated vaccines will be tested in order to obtain the most immunogenic product.

- Japanese Encephalitis Killed Vaccine is extracted and purified from infected mouse brain tissue by a Japanese company (Biken), and has been shown to reduce the incidence of disease in endemic regions of the world. It is currently being administered as an investigational vaccine since it is not licensed in this country.

- Schistosome Topical Antipenetrant is a niclosamide-based lotion originally designed at WRAIR and then formulated for application to human skin by Milcs Laboratory. The niclosamide lotion prevents the penetration of free swimming schistosomal larva.

- Insect/Arthropod Repellent, Clothing Impregnant is a chemical treatment of permethrin to the Battle Dress Uniform to provide protection of the covered areas from insect/arthropod bites. One treatment lasts for the entire life of the uniform. EPA registration will be sought for several volumes of the chemical in order to allow individual or mass application to uniforms.

- Chikungunya Vaccine is a live attenuated virus vaccine obtained by growing the virus in cultured human lung cells at USAMRIID. The Salk Institute produced the experimental lots under regulatory guidelines for testing in humans, and following additional human testing it will be stored in a lyophilized form as a contingency vaccine.

- Live Attenuated Dengue Type 4 Vaccine is a non-disease producing strain of dengue 4 virus produced by WRAIR by growing the virus in cultured primary dog kidney cells and then in fetal rhesus monkey lung cells. The cell culture supernatant contains the attenuated virus which was lyophilized for long-term storage and shown to pass regulatory safety tests. After satisfactory human studies, the live vaccine will be combined with live vaccines for the other dengue virus serotypes.

- Klebsiella/Pseudomonas Human Immune Globulins will treat opportunistic infections in burn and wound patients. The immune globulins will be obtained from the plasma of volunteers immunized with Klebsiella and Pseudomonas vaccines. Each vaccine contains antigens from multiple serotypes of the organism, and was shown to induce antibodies in volunteer studies involving a collaborative effort between WRAIR and the Swiss Serum Institute.

- Q Fever Vaccine (Chloroform-Methanol Residue (CMR)) is a formalin inactivated vaccine prepared at the Salk Institute from rickettsia that are grown in embryonated eggs. The extraction with chloroform-methanol was devised at the USAMRIID, and was shown to eliminate severe skin reactions in animals inoculated with earlier vaccine. The vaccine is for BW defense.

- Adenovirus Vectored Hepatitis B Vaccine was developed by Wyeth Laboratories by using recombinant DNA technology to incorporate the hepatitis B surface antigen gene into adenovirus type 7. This engineered adenovirus produces both hepatitis B and adenovirus 7 antigens in infected cell culture, and has passed regulatory safety tests. The Army will test the vaccine in volunteers and use it in recruits if it can be licensed.

- Botulinal Toxoids, Types F & G, will be used in a polyvalent product for military personnel being deployed to an area where there is a potential threat use of Clostridium botulinum toxin as a BW agent. The toxins will be extracted from cultures of the organism that produce either types F or G toxin, inactivated with formalin to produce the toxoid, and tested separately and then together for the ability to produce toxin neutralizing antibodies in humans.

- Lassa Fever Immune Plasma is an immune globulin used to treat Lassa fever infections. The collection of human immune plasma in Africa is an ongoing contract effort. USAMRIID performs laboratory tests and selects the plasma units with sufficient antibody titers for fractionation into immune globulin.

- Stroma-Free Hemoglobin is an oxygen-carrying blood substitute for use in field medical units. Baxter-Travenol produced several batches of cross-linked hemoglobin that will be evaluated in preclinical tests.

- Salk Institute Vaccine Production Facility is a manufacturing facility dedicated exclusively to the production of vaccines and diagnostic reagents under Federal regulatory guidelines. The facility is managed by a task order contract for scheduling production of vaccines and reagents.

- University of Maryland Vaccine Testing Facility is used for evaluating vaccines in human safety and efficacy trials. The trials are done either in the 32-bed isolation ward or on an outpatient basis. Each trial is performed under a task order.

MAJOR ACCOMPLISHMENTS

- A Milestone III IPR held in July 1988 approved transition of the Insect/Arthropod Repellent Lotion to production and deployment. Environmental Protection Agency (EPA) registration was granted in July 1988, NSN 6840-01-254-3982 was assigned in August 1988.

- Five military medical centers are participating in clinical trials of the J-5 human Monoclonal Antibody. Volunteers with clinically diagnosed gram negative septic shock have been enrolled in the treatment protocol.

- Mice vaccinated with recombinant Vaccinia Vectored VEE Vaccine virus developed virus-specific antibodies and were capable of surviving intraperitoneal challenge with virulent virus. Four of six monkeys developed neutralizing antibodies following recombinant virus immunization.

- A special In-Process Review (IPR) was held in August 1988 for approval to change the acquisition strategy of the Rapid Identification System to that of a modified Non-Developmental Item (NDI). Five companies were willing to participate in no-cost agreements. Three were chosen to incorporate USAMRDC reagents for plague into their commercial products and supply 50 assays for evaluation in Federal laboratories. Thus far, two companies have submitted kits that will identify plague antigen in <30 minutes. A Capstone JSOR was approved in April 1988.

- Expanded Phase I safety tests of Argentine Hemorrhagic Fever Vaccine involving 73 volunteers were completed in Argentina with 100 percent seroconversion and no adverse reactions. In a field trial currently in progress, more than 5000 at-risk Argentine volunteers have received the vaccine. A JSOR for Hemorrhagic Fever Vaccines was approved in November 1988.

- The Chilean Ministry of Health, PAHO, and WRAIR cooperated to immunize 40,000 volunteers in a double blind study of N. Meningitidis Vaccine. Controls received a licensed Group C vaccine. The study population is still being monitored for group B disease.

- A Phase I clinical trial for a new lot of Tularemia Vaccine (modified production protocol) was initiated at USAMRIID. However, because liver enzyme changes were noted in three of nine vaccinees, the Phase I trial has been suspended, pending review of clinical records on recipients of the old vaccine as well. A JSOR for Tularemia Vaccine was approved in October 1988.

- The final section of a New Drug Application (NDA) for Ribavirin describing the clinical field trials has been assembled and is being reviewed.

- Two candidate Shigella Vaccines are currently undergoing refinement and a third candidate vaccine, composed of a strain of Shigella flexneri genetically engineered to be avirulent, is ready for tests in volunteers.

- The Capstone JSOR for Falciparum Malaria Vaccine was approved on 29 November 1988. Studies in Europe indicated that a recombinant protein covalently bound to Pseudomonas toxin A generated consistently higher human antibody levels than the same protein admixed with alum.

- An IND was submitted for an adjuvantized recombinant protein Vivax Malaria Vaccine. Phase I studies have been initiated at USAMRIID. To date, there have been no adverse reactions to this vaccine.

- The Fort Lewis Phase II study of the inactivated Hepatitis A Vaccine was completed and showed that a reduced number of inoculations (3) were effective at inducing an antibody response. Neutralizing antibody was detected in 20 out of 23 vaccinees. An Investigational New Drug (IND) Application was submitted and Phase I protocol approved to evaluate the safety and immunogenicity of a killed vaccine produced by Smith, Kline and French.
- Licensure assistance is being provided by USAMMDA to the manufacturer (Biken) of Japanese Encephalitis Killed Vaccine based on the successful Army efficacy study in Thailand carried out by WRAIR.

- The Test and Evaluation Master Plan for Schistosome Topical Antipenetrant was approved by a Joint Test Integration Working Group. The JSOR was approved by the Army Surgeon General, with TRADOC concurrence, and plans were initiated for Phase I human safety studies at Johns Hopkins University.

- Agreement was reached to field multiple methods of permethrin impregnation of the Insect/Arthropod Repellent, Clothing Impregnant with an Individual Dynamic Adsorption Kit (for individual use), 2-gallon sprayer method (for company size unit use), and pad roll method (for industrial application). Continued technical testing showed negligible permethrin residue in adsorption kit bags, and that perspiration and steam pressing of Battle Dress Uniforms (BDUs) had no degrading effect on the permethrin.

- Extended Phase I testing brings to 51 the number of volunteers at USAMRIID who have received Live Attenuated Chikungunya Vaccine. There were no adverse reactions and all volunteers produced antibodies to the virus.

- Dengue 4 Vaccine Phase I safety studies were completed showing that the attenuated vaccine was safe and induced an immune response in five out of eight individuals.

- A Request for Proposal (RFP) has been advertised to obtain immune plasma to prepare Klebsiella/Pseudomonas Immune Globulins from volunteers immunized with the concommitant vaccines.

- Preclinical testing of the irradiated CMR Q Fever Vaccine is virtually completed. A JSOR for Q Fever vaccines was approved in April 1988.

- A contract was awarded in June 1988 for the manufacture of Botulinal Toxoids, Types F & G. Small amounts of type F toxin have been produced and are ready for toxoiding.

• A new contract was initiated with the Salk Institute Vaccine Production Facility on 1 April 1988. They completed harvesting the Q Fever vaccine and approximately 100,000 doses were taken through the extraction and irradiation process. Preclinical testing will be completed and the IND submitted soon. In collaboration with WRAIR, Hepatitis A vaccine production was initiated. This vaccine will be a purified formalin inactivated product. Diagnostic and cell culture reagents for various Army relevant vaccines were produced as needed. Preclinical testing was conducted for Junin and Rift Valley Fever attenuated vaccines. A mixture of allantoin and urea was found to stabilize Rift Valley Fever virus.

• Two tasks involving evaluation of candidate Shigella sonnei vaccines were completed this year by the University of Maryland Vaccine Testing Facility. Although these vaccines were safe, there was no significant difference in protection in a challenge study between the volunteers who were vaccinated and unimmunized control patients. A study to compare two routes of administration of Hepatitis B vaccine was initiated. Volunteers will receive one or two doses of vaccine via intradermal and intramuscular routes. Serological conversion will be evaluated after 1 year. Another task initiated this year will evaluate immunogenicity of Pseudomonas and Klebsiella vaccines given simultaneously and at a 2-week interval. Initial clinical protocols were drafted for another candidate Shigella vaccine (Shigella flexneri, type Y). Preliminary studies to evaluate a Vi-positive typhoid vaccine strain were initiated this year. This product is an oral vaccine combining antigens found in the Ty21a strain with the Vi antigen.

PROJECTIONS

• Procurement is under way for the Insect/Arthropod Repellent Lotion by the Defense General Supply Center. The new product is expected to be available for field use by 4Q89.

• The inactivated Rift Valley Fever Vaccine will be transitioned from advanced development to a contingency-deployment status 3Q89.

• Expanded clinical trials will be carried out with the J-5 Human Monoclonal Antibody. Results of the trials from both the civilian and military sector should enable licensure of the product by Centocor.

• Equine studies will determine the effect of the Vaccinia Vectored VEE Vaccine on preventing infection in the natural host.

- Commercial antigen-detection test kits, reformatted for detection of plague antigen, will be evaluated at USAMRIID, WRAIR and CDC in 3QFY89. Procurement procedures for the Rapid Identification System will begin in 4QFY89 for 1000 assay systems for each of four agents from up to three companies which have demonstrated that they have rapid, easy to use operating systems.

- The Phase III field trial will continue in 1989, with the Argentine Hemorrhagic Fever Vaccine being administered to an additional 1000 or more Argentine volunteers from the at-risk population. Initial 12-month clinical and serological data will be obtained for the first group of approximately 6000 vaccinees by 4QFY89.

- Collaborative agreement with the National Bacteriology Laboratory of Sweden will provide us with additional human use data on the Tularemia Vaccine.

- The genetically engineered Shigella flexneri Vaccine will be tested in Phase I clinical trials at the University of Maryland Vaccine Testing Facility.

- An IND for the Plasmodium Falciparum Vaccine coupled to toxin A has been submitted and the protocol is in the approval process for Phase I/IIA testing under contract at Johns Hopkins Center for Immunization Research. Protocols for other adjuvants have been approved to begin testing at the Naval Medical Center, Bethesda, Maryland.

- Extended safety and immunogenicity studies of Plasmodium Vivax Vaccine will be carried out with additional volunteers.

- An IND is in final preparation for submission to test an Attenuated Hepatitis A Vaccine at USAMRIID, and the Phase I protocol is in the approval process.

- Coordination was effected with Cairo, Egypt, for human efficacy studies of the Schistosome Topical Antipenetrant in 1989 and the Army Operational Test and Evaluation Agency scheduled soldier acceptance and user testing for July 1990.

- Genetic stability and transmissibility of the Chikungunya Vaccine in mosquitoes will be addressed.

- A new study of Dengue 4 Vaccine will evaluate immunogenicity in yellow fever immune individuals and expand the number of flavivirus naive vaccinees. Transmission by vector mosquitoes will also be evaluated in this study.

- An IND application for Q Fever Vaccine CMR, Irradiated, is in preparation for submission in 2QFY89. Phase I clinical trials will commence in 3QFY89.

- Allantoin will be evaluated by the Salk Institute Vaccine Production Facility as a generic stabilizer for attenuated viruses. Certified vaccinia vector seed stocks will be produced and characterized as a carrier for several recombinant vaccines.

- Future studies by the University of Maryland Vaccine Testing Facility include evaluation of typhoid vaccine and Shigella immune milk. Hepatitis B titers will be determined on the 12-month serum samples from volunteers immunized with inactivated Hepatitis B vaccines, both recombinant and serum derived.

PHARMACEUTICAL SYSTEMS
PROJECT MANAGEMENT DIVISION

THE PROGRAM

INTRODUCTION

The Pharmaceutical Systems Project Management Division centrally manages the development and the initial production of pharmaceutical products (antidotes and drugs), related drug delivery systems (autoinjectors and transdermal patches), and decontamination products. These products are fielded as preventive, protective, and therapeutic modalities for use against chemical and biological warfare threats, certain endemic diseases, and the treatment of combat casualties.

MILITARY RELEVANCE

U.S. military forces must be prepared to serve anywhere in the world against any threat. This could result not only in conventional injuries sustained during combat but exposure to chemical and biological warfare agents as well as exposure to endemic diseases not commonly found in the United States. The development of products against these threats will help save lives, sustain the fighting force, and enhance return to duty.

OBJECTIVES

The objectives of this division are to develop pharmaceuticals to be used for prophylaxis, immediate treatment, and definitive treatment against a wide variety of naturally occurring diseases, threat force use of chemical and biological agents, and combat-generated injuries. These pharmaceuticals include those for use following exposure to organophosphorus compounds, vesicants, and cyanide, and those to protect or treat soldiers suffering from malaria, schistosomiasis, and leishmaniasis. In addition, a kit to decontaminate the skin following exposure to chemical warfare agents or toxins is undergoing development as is an antidote against the oral ingestion of toxins. From a more conventional aspect, blood replacement fluids, improved antimicrobial skin dressings, and more field-durable analgesics are under development.

PRODUCT DESCRIPTIONS

- The XM291 Skin Decontaminating Kit (SDK) is a resin-based system being developed for joint service use. It will replace the current M258A1 Personal Decontamination Kit and the M58A1 Training Aid. The XM291 is envisioned as a superior, safe and effective skin decontaminating system for use against multiple percutaneous chemical threat agents. The SDK will be transitioned to the U.S. Army Armament, Munitions, and Chemical Command (AMCCOM) for production and deployment. Initial production of 1.8 million kits will be accomplished by AMCCOM under phase II of the current development contract.

- Hypertonic Saline Dextran (HSD) is a safe and effective, small-volume product suitable for rapid field administration that can be used to resuscitate and stabilize hypovolemic shock casualties. A Collaborative Research and Development Agreement is on-going with Pharmacia and involves clinical trials at three sites. To date, results of the clinical trials have demonstrated the safety of the product, however, protocol modifications will be required to address efficacy.

- A Convulsant Antidote for Nerve Agent (CANA) is required to prevent or ameliorate convulsions in severe nerve agent casualties. Anticonvulsants such as diazepam prevent these convulsions which can result in brain injury. An autoinjector containing only an anticonvulsant will be issued to soldiers and administered by Buddy Aid to those individuals incapacitated by nerve agents.

- A proposed Toxin Antidote (Superactivated Charcoal) is a commercially available activated charcoal preparation with three times the surface area of Activated Charcoal USP. Documented evidence shows that this product could be used as an antidote in a variety of poisonings, including mycotoxins.

- A New Drug Application (NDA) for the antimalarial drug, Mefloquine Hydrochloride, was filed with the Food and Drug Administration (FDA) in February 1986. The indications contained in the NDA were for the prevention and treatment of chloroquine resistant Plasmodium falciparum malaria. At a November 1987 meeting between the FDA and the applicants, the FDA requested that the biopharmaceutical information of the NDA be reorganized and submitted as a supplement to facilitate rapid review. This task was accomplished and results submitted to FDA in December 1987.

- Halofantrine will be a safe and effective treatment and prophylaxis for P. falciparum malaria resistant to Mefloquine. All preclinical and clinical studies have either been completed or are nearing completion for a treatment indication. There is a No-Dollar Agreement with Smith, Kline and French (SKF) for joint development of this product.

- Pyridostigmine Sustained Release is envisioned as a superior pretreatment for use against nerve agent poisoning. When used in combination with atropine and 2-PAM, pyridostigmine is effective against all known nerve agents and is notably effective against soman.

- The Medical Aerosolized Nerve Agent Antidote (MANAA) is an atropine aerosol inhalant used by medics for the supplemental treatment of nerve agent casualties after adequate injectable atropine has been given. The expected role of MANAA is to deliver atropine to the airway of spontaneously breathing and sufficiently lucid nerve agent casualties. The aerosol is intended for use at forward medical care facilities including battalion aid stations. Drug delivery by inhalation requires a coordinated inspiratory effort upon aerosol actuation. To be in a position to approve an NDA, the FDA needs a study which demonstrates that military medics can adequately administer the aerosol to naive normal subjects who are unfamiliar with the product.

- Morphine Repackaging is needed to provide an analgesic that meets the field requirements of extended stability, greater durability and rapidity of use, and is tamper evident. Morphine stocks in the inventory are over 25 years old and are beginning to deteriorate.

- A Multichambered Autoinjector (MA) (single barrel) for the administration of nerve agent antidotes (2 mg atropine, 600 mg 2-PAM Cl) is being evaluated. The MA is a single autoinjector which contains therapeutic drugs in separate chambers and injects both antidotes through a single needle. A clinical study at the Department of Clinical Investigation, Madigan Army Medical Center, suggested that the injection of atropine and 2-PAM Cl into the same injection site adversely affects the absorption of atropine. Technical studies are currently underway to resolve this issue.

- An improved Antimicrobial Dermal Dressing (ADD) will be capable of providing sustained release of antimicrobial agents at the site of dermal injury to prevent infection and enhance wound healing.

- The British Antilewisite, Improved Ophthalmic Formulation (I-BAL) program has undergone considerable reevaluation in terms of development maturity. In program reviews conducted by both the Scientific Steering Committee and a Joint Working Group, a determination was made that considerable basic research is still required before this effort can continue in advanced development. Information which is necessary includes a complete chemical description of the candidate formulation, preclinical toxicology, preclinical efficacy, and stability data with the candidate formulation.

MAJOR ACCOMPLISHMENTS

- Final approval was obtained for the JSOR for the XM291 Skin Decontaminating Kit (SDK). The Initial Operational Test and Evaluation (IOT&E), conducted at Fort Bragg, NC, was completed 2Q88. A final camera ready copy of the Joint Service Operator's Manual has been prepared. A draft technical data package (TDP) for manufacture and competitive procurement of the SDK was prepared. A contract option for TDP validation, first article test, and low rate initial production was awarded to Rohm and Haas Company in November 1988.

- Non-clinical studies on Hypertonic Saline Dextran (HSD) were completed by LAIR ahead of schedule and within cost guidelines. Clinical trials accrued 316 patients, sufficient for the first interim data analysis. Technical Testing was completed in October at the U.S. Army Biomedical Research and Development Laboratory.

- The AMEDD Tech Committee was presented a risk assessment of Convulsant Antidote for Nerve Agent (CANA). Based on this information, they sanctioned the continued development of CANA. Studies were conducted at USABRDL and the Human Engineering Laboratory to determine optimum flange design to enable soldiers to differentiate this autoinjector from others that they will carry. An Operational and Organizational (O&O) Plan was approved by TRADOC. The Deputy Chief of Staff for Operations and Plans approved the JSOR in November. The Test Integration Working Group (TIWG) was held in January and a Test and Evaluation Management Plan (TEMP) was drafted and approved. An RFP for the development and Low Rate Initial Production was released in August.

- A market survey has been conducted for Toxin Antidote (Super...tivated Charcoal) and an informal transition group formed to facilitate both specification definition and transition as a replacement for the currently used activated charcoal.

- Additional data from a clinical trial with Mefloquine, conducted in the summer of 1988, were submitted to the FDA in December. The product is scheduled for Scientific Rounds at the FDA in February 1989.

- SKF is expected to file for regulatory approval of Halofantrine in the U.S. this year. Toxicology protocols have been designed and task orders initiated for preclinical work needed prior to initiation of prophylactic human studies.

- Three candidate formulations of Sustained Release Pyridostigmine, obtained under contract or No-Dollar Agreement, underwent clinical studies. A Milestone I IPR was held which advanced the development of the product in package design and testing. Documentation for the IND file at the FDA was updated, and toxicological studies were initiated to establish the safety regarding its teratological and reproductive effects. Studies were begun on the possible interaction of Pyridostigmine on human thermoregulatory physiology under various conditions.

- Meetings held with the FDA on Medical Aerosolized Nerve Agent Antidote resulted in a decision that the only additional requirement needed for the NDA was a study to evaluate the ability of naive individuals to use the inhaler.

- The AMEDD Tech Committee was briefed in December on the recommendations of the expert panel convened to evaluate injector devices for the delivery of morphine in the field. The AMEDD Tech Committee approved the 10 mg Morphine Autoinjector as the replacement item for the morphine syrette and sanctioned a program to complete development and fielding. Three No-Dollar Agreements were initiated to complete this effort. A Milestone I IPR delineated additional developmental issues to be resolved in Technical testing.

- The Combat Developer (AHS) forwarded the Required Operational Capability (ROC) for the Antimicrobial Dermal Dressing (ADD) to TRADOC for approval. A Collaborative Research and Development Agreement was initiated to evaluate products that could satisfy the military requirements of a sustained release product. A study was conducted to demonstrate the efficacy of the Army prototype ADD against bacteria in log growth phase. User Testing was conducted in August and resulted in concerns over the ability of the backing to adhere properly.

- A capstone JSOR (Family of Vesicant Antidotes) has been approved at HQDA for I-BAL.

PROJECTIONS

- TDP validation and First Article Test for the XM291 Skin Decontaminating Kit will be concluded and a Milestone III IPR will be held 1Q90.

- Final Technical Testing (TT) of the XM291 is in progress and is scheduled for completion 2Q89.

- Meetings with the FDA will resolve issues on the requirements for the Hypertonic Saline Dextran (HSD) clinical studies. A Milestone I/II IPR is scheduled for 3Q90.

- A Milestone I/II IPR will be held for the Convulsant Antidote for Nerve Agent during 1Q89. A development contract will be awarded during the 2Q89.

- A Milestone I/III IPR for the Toxin Antidote (Superactivated Charcoal) will be held 2Q89 and this product will be transitioned to the readiness component.

- Halofantrine, for a treatment indication for malaria, will have a Milestone III IPR 4Q89.

- Planning continues for the User Test for the packaging of Pyridostigmine which is scheduled for July 1989.

- Clinical studies for the Medical Aerosolized Nerve Agent Antidote are scheduled to be completed during the 2Q89. A Milestone II/III IPR will be held 3Q89.

- An Abbreviated New Drug Application (ANDA) will be filed for the Morphine Autoinjector with approval expected during the 3Q89. A correspondence IPR will be held to transition the product to Production and Deployment.

- A draft JSOR for the Multichambered Autoinjector is being staffed and approval is expected 3Q89.

- Cooperative Research and Development Agreements will be initiated to identify a product that meets the military requirements of an Antimicrobial Dermal Dressing. A Milestone I IPR will be held 4Q89.

- A Milestone II/III IPR for the antimalarial drug Enpiroline will be held 4Q89.

- A Milestone III for the antileishmanial drug Pentostam will be held 4Q89.

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Caldwell, Donald W. REFLUPS project briefing to Special Tri-Service General Officer Review, Fort Detrick, MD, May 1988

Channing, Eugene S. "Ballistic-Laser Protective Spectacles," Military District of Washington Optometrist Continuing Education Program, Washington, DC, February 1988

Channing, Eugene S. "Modifications, Trainings, and First Article Test Findings for Ballistic-Laser Protective Spectacles," Army Eye Protection Program Joint Working Group, Woodbridge, VA, March 1988

Channing, Eugene S. "Ballistic-Laser Protective Spectacles," 1988 Military Optometry AMEDD Professional Short Course, Aurora, CO, September 1988

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Channing, Eugene S. "Optometry Field Set Fielding," 1988 Military Optometry AMEDD Professional Short Course, Aurora, CO, September 1988

Goeringer, Fred "Clinical Engineering as a Sub-Speciality for Medical Logisticians," Medical Logistics Management Post Graduate Short Course, Aurora, CO, May 1988

Goeringer, Fred "Digital Imaging Network Systems: Network Standards for the Battlefield," American College of Radiologists/National Electronics Manufacturing Association Conference, Los Angeles, CA, September 1988

Goeringer, Fred "Digital Imaging Network Systems: Military Applications," Electronic Imaging 88 - Imaging for Medicine Conference, Boston, MA, October 1988

Goeringer, Fred "Digital Imaging Network Systems: Military Applications," Association of Military Surgeons of the United States Conference, San Antonio, TX, October 1988

Goeringer, Fred "Digital Imaging Network Systems: Military Applications," AMEDD Teaching Chiefs Conference, Denver, CO, November 1988

Green, Martin D. Pyridostigmine project briefing, U.S.-Israel 1988 Bilateral Military Medical Research and Development Symposium, Fort Detrick, Frederick, MD, 11 July 1988

Harrington, Donald G. Project briefing on SDK Requirements Documents for General Armstrong, Office of the Deputy Chief of Staff for Operations, Washington, DC, 17 June 1988

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Hillberg, Owen E. Morphine project briefing, Office of The Surgeon General, Army Medical Department Technical Committee, Falls Church, VA, 8 November 1988

Johnson-Winegar, Anna. Advanced Development Process, Joint Meeting of USAMRDC-Israel Defense Forces, in Israel, March 1988

Johnson-Winegar, Anna. Chaired sub-session on viral diseases and toxins at the Army Science Conference, Fort Monroe, VA, October 1988

Johnson-Winegar, Anna. Chaired sub-session on Acquired Immune Deficiency Syndrome (AIDS) at the Mid-Atlantic Regional American Society for Microbiology, Williamsburg, VA, December 1988

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Nielsen, Carl J. BAL briefing to Commander and Staff, Defense Depot, Mechanicsburg, PA, 11 August 1988

Oaks, Stanley C. 102nd ARCOM Medical Symposium, Presentation on "Development of Medical Materiel for the U.S. Military," St. Louis, MO, February 1988

Pick, Robert O. Briefing on Chemical Defense, SDK, Treatment andPretreatment, Board on Army Science and Technology, Fort Detrick, Frederick, MD, 14 December 1988

Roberts, Lyman, W. Presentation on Medical Entomology given to Biennial Army Medical Entomology Training Course, San Antonio, TX, February 1988

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SEMINARS AND MAJOR TRAINING EVENTS

Bateman, Edgar L. Logistics Support Analysis, ALMC, Ft Lee, VA, August-September 1988

Bateman, Edgar L. Materiel Acquisition Management course, ALMC, Ft Lee, VA, January-March 1988

Bateman, Edgar L. MANPRINT Training, St Louis, MO, November 1988

Brandt, Walter E. Chairman, WHO Steering Committee on Dengue. Geneva, Switzerland, June 1988

Brandt, Walter E. WHO Scientific Advisory Group of Experts. Geneva, Switzerland, July 1988

Brandt, Walter E. American Society of Tropical Medicine and Hygiene, Washington, DC, Scientific Program Committee, December 1988

Caldwell, Donald W. Army Medical Department MANPRINT Seminar, Ft Sam Houston, TX, January 1988

Caldwell, Donald W. Acoustical Society of America, Honolulu, HI, November 1988

Channing, Eugene S. Military District of Washington Optometrists Continuing Education Program, Washington, DC, February 1988

Channing, Eugene S. First Annual Occupational Vision Consultants Course, Aberdeen Proving Ground, MD, June 1988

Channing, Eugene S. 1988 Military Optometry AMEDD Professional Short Course, Aurora, CO, September 1988

Channing, Eugene S. Use of Contact Lenses Under Adverse Condition Symposium, San Antonio, TX, November 1988

Channing, Eugene S. Laser/Ballistic Eye Protection Protective Mask Workshop, Natick, MA, December 1988

Clawson, Ronald E. Basic Supervision Seminar, Baltimore, MD, March 1988

Clawson, Ronald E. Personnel Management for Executives Conference, Taiment Resort, PA, May 1988

Clawson, Ronald E. Workshop on Chemical Operations in Cold Weather, USAMRICD, Aberdeen Proving Ground, MD, August 1988

Clawson, Ronald E. Safety and Efficacy in Military Medical Research, Ft Detrick, Frederick, MD, September 1988

Clawson, Ronald E. Good Clinical Practice Course, Center for Professional Advancement, East Brunswick, NJ, November-December 1988

Cole, Francis E. Hazard Communication Course, Ft Detrick, MD, August 1988

Fung, Kathleen P. English 101-English Composition, Frederick Community College (FCC), Frederick, MD, November 1988-April 1989

Goeringer, Fred Medical Logistics Management Post Graduate ShortCourse, Aurora, CO, May 1988

Green, Martin D. Federation of American Societies for Experimental Biology, Las Vegas, NV, May 1988

Green, Martin D. Safety and Efficacy in Military Medical Research, Ft Detrick, MD, September 1988

Green, Martin D. Jewish Lay Leader Conference, Miami, FL, November-December 1988

Guessford, Kay E. Basic Medical Terminology, Ft Detrick, MD, March 1988

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Hawley, Robert J. Material Acquisition Management Course, Ft Lee, VA, June 1988

Hillberg, Owen E. American Society of Hospital Pharmacists Meeting, Dallas, TX, December 1988

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Johnson-Winegar, Anna. Food and Drug Law Institute, Prescription Drug Advertising, Washington, DC, January 1988

Johnson-Winegar, Anna. American Society for Microbiology, Miami, FL, May 1988

Johnson-Winegar, Anna. Baltimore Federal Executive Board Seminar for Federal Women's Program, Baltimore, MD, September 1988.

Lehmann, Craig R. 1988 U.S. Air Force Pharmacy Seminar, Wichita Falls, TX, April 1988

Lehmann, Craig R. American Association of Pharmaceutical Scientists, Atlantic City, NJ, June 1988

Nielsen, Carl J. Test and Evaluation Management Course, ALMC, Ft Lee, VA, May 1988

Oaks, Stanley C. Society of Armed Forces Medical Laboratory Scientists (SAFMLS), Reno, NV, March 1988

O'Brien, John C. Skin Product Development, E. Brunswick, NJ November 1988

O'Brien, John C. National Council of University Research Administrators, Washington, DC, November 1988

Parra, Deanna W. Budget Formulation, Ft Detrick, MD, June 1988

Parra, Deanna W. Introduction to Business, FCC, Frederick, MD, August-December 1988

Pelosi, John J. American Society of Clinical Oncology, New Orleans, LA, May 1988

Pick, Robert O. Army Medical Department MANPRINT Seminar, San Antonio, TX, January 1988

Pick, Robert O. Executive Management Course, DSMC, Ft Belvoir, VA, January 1988

Pick, Robert O. American Chemical Society, Los Angeles, CA, September-October 1988

Priebe, Rebecca A. VAX System Management I, Landover, MD, January 1988

Priebe, Rebecca A. Security in Automated Systems, Ft Detrick, MD, September 1988

Priebe, Rebecca A. Integrating MacIntosh into VAX System Networks, Rockville, MD, November 1988

Rice, Robert M. American Society of Tropical Medicine and Hygiene, Washington, DC, December 1988

Routzahn, Ricky L. Budget Formulation, Ft Detrick, MD, June 1988

Roy, Michael J. Good Laboratory Practices, Deerfield Beach, FL, November 1988

Schiefer, Bernard A. Medical Entomology Professional Postgraduate Short Course, San Antonio, TX, February 1988

Sheffer, Linda J. Intermediate Accounting IV, FCC, Frederick, MD, December 1987-May 1988

Sheffer, Linda J. Advanced Lotus, Ft Detrick, MD, January 1988

Sheffer, Linda J. Introduction to Business, FCC, Frederick, MD, January-May 1988

Sheffer, Linda J. Principles of Economics, FCC, Frederick, MD, August-December 1988

Sheffer, Linda J. Auditing, FCC, Frederick, MD, August-December 1988

Sullivan, Clara V. Basic Cataloging, Atlanta, GA, June 1988

Sullivan, Clara V. Human Relations, FCC, Frederick, MD, January-May 1988

Sullivan, Clara V. AMEDDPAS, Ft Sam Houston, TX, May 1988

Twist, Anne P. Understanding Overhead in Government Contracts, Boston, MA, February-March 1988

Williams, Linda M. Integrated Logistics Support (Basic), USAMC, Alexandria, VA, April 1988

Williams, Linda M. R&D Orientation, ALMC, Ft Lee, VA, April 1988

Williams, Linda M. MANPRINT Staff Officers Course, Alexandria, VA, May 1988

Williams, Linda M. ILS Advance Course, ALMC, Ft Lee, VA, June 1988

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Dr. Chris Roberts, Mr. Tom Billingsley, and Ms Camp. Smith-Nephew, UK. Discussion of industrial capabilities in medicated dressings, 29 February 1988

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RADM D.F. Hagen, Navy Surgeon General's Office, MG Robert H. Buker, Deputy Surgeon General, OTSG, MG William P. Winkler, DASD(MR), RADM Joseph S. Cassells, Commander, Naval Medical Command. Resuscitative Fluids Production System (REFLUPS) In-Process Review, 12 May 1988

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